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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,434	02/08/2002	James Baumgardner	22253-70649 (N2377)	2826

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT PAPER NUMBER

3737

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/071,434

Applicant(s)

BAUMGARDNER ET AL.

Examiner

Shawna J. Shaw

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2001 and 01 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/1/2002</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the system or device for producing high resolution, three-dimensional images of pulmonary ventilation (V) in the lung and all its components must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

2. Claims 14 and 15 are objected to because of the following informalities: In claim 14 line 1, "The" should be changed to --A--. In claim 15, it is not clear how the "computer-readable signal-bearing medium" is connected, or relates to, the rest of the components. In addition, in lines 10 and 11, it is not clear what "therefrom" is referring to. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what structure(s) from the specification or drawings correspond to the 'means' for collecting, dividing, synchronously imaging, imaging, spatially co-registering and computing.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

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application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Maki et al. "Recent Advances in Pulmonary Imaging."

Maki et al. discloses a method and apparatus for performing quantitative combined 3D MR imaging of ventilation and perfusion (V/Q) (p. 1392-93), including administering a hyperpolarized gas, such as  $^3\text{He}$ . Maki et al. additionally disclose performing perfusion imaging using gadolinium or arterial spin-tagging methods (p. 1390-91).

5. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiler et al.

Weiler et al. disclose a method and apparatus for performing combined ventilation and perfusion imaging using a hyperpolarized gas, such as  $^3\text{He}$ , including collecting 3D MR image data and quantitatively calculating V/Q and perfusion therefrom (col. 5 and col. 8 lines 5-57).

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

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35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiler et al.

Regarding claims 4 and 5, Weiler et al. does not explicitly address using gadolinium or arterial spin tagging for imaging lung perfusion, although does disclose that the  $^3\text{He}$  imaging may be combined with a second imaging agent such as a paramagnetic chelate, superparamagnetic agent, etc. (col. 8 lines 42-47). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a gadolinium-based imaging agent, or an arterial spin tagging technique (as admitted by applicant on pages 7 and 14 to be known, for example in 5,402,785) because Applicant has not disclosed that such an imaging agent or technique provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the secondary imaging agents of Weiler et al. because all perform the same function of enhanced perfusion imaging.

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7. Claims 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiler et al. or Maki et al. in view of Giger et al.

Regarding claims 6-13, Weiler et al. and Maki et al. differ from the claimed invention in that image processing and co-registration algorithms are not addressed specifically. Giger et al. generally demonstrates that co-registration of digital lung images and V/Q data are well known to obtain discrete structural and morphological data. In addition, applicants' admit on page 16 lines 5-11 that such co-registration algorithms are well established. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to co-register lung image data, e.g., as taught by Giger et al., in the invention as taught by Weiler et al. or Maki et al. to obtain accurate complementary functional and morphological information of the lung.

Regarding claims 14 and 15, Weiler et al. and Maki et al. differ from the claimed invention in that an image processing and spatial co-registration means are not discussed in detail. Giger et al. generally demonstrates that co-registration of digital lung images and V/Q data are well known to obtain discrete structural and morphological data. In addition, applicants' admit on page 16 lines 5-11 that such co-registration algorithms are well established. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use the computerized image registration means of Giger et al. in the invention as taught by Weiler et al. or Maki et al. to obtain accurate complementary functional and morphological information of the lung in an automated manner.

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**Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached from 6:45 a.m. – 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw  
Primary Examiner  
Art Unit: 3737  
09/02/2004